R156. Commerce, Occupational and Professional Licensing.
R156-37. Utah Controlled Substances Act Rules.
R156-37-101. Title.

These rules are known as the "Utah Controlled Substances Act Rules."

R156-37-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 37, as used in Title 58, Chapters 1 and 37, or these rules:

(1) "DEA" means the Drug Enforcement Administration of the United States Department of Justice.

(2) "NABP" means the National Association of Boards of Pharmacy.

(3) "Principle place of business or professional practice", as used in Subsection 58-37-6(2)(e), means any location where controlled substances are received or stored.

(4) "Schedule II controlled stimulant" means any material, compound, mixture or preparation listed in Subsection 58-37-4(2)(b)(iii).

(5) "Unprofessional conduct", as defined in Title 58 is further defined in accordance with Subsections 58-1-203(1)(e) and 58-37-6(1)(a), in Section R156-37-502.

R156-37-103. Purpose - Authority.

These rules are adopted by the division under the authority of Subsections 58-1-106(1)(a) and 58-37-6(1)(a) to enable the division to administer Title 58, Chapter 37.

R156-37-104. Organization - Relationship to Rule R156-1.

The organization of this rule and its relationship to Rule R156-1 is as described in Section R156-1-107.

R156-37-301. License Classifications - Restrictions.

(1) Consistent with the provisions of law, the division may issue a controlled substance license to manufacture, produce, distribute, dispense, prescribe, obtain, administer, analyze, or conduct research with controlled substances in Schedules I, II, III, IV, or V to qualified persons. Licenses shall be issued to qualified persons in the following categories:

(a) pharmacist;
(b) optometrist;
(c) podiatric physician;
(d) dentist;
(e) osteopathic physician and surgeon;
(f) physician and surgeon;
(g) physician assistant;
(h) veterinarian;
(i) advanced practice registered nurse;
(j) certified nurse midwife;
(k) certified registered nurse anesthetist;
(l) Class A pharmacy-retail operations located in Utah;
(m) Class B pharmacy located in Utah providing services to a target population unique to the needs of the healthcare services required by the patient, including:
(i) closed door;
(ii) hospital clinic pharmacy;
(iii) methadone clinics;
(iv) nuclear;
(v) branch;
(vi) hospice facility pharmacy;
(vii) veterinarian pharmaceutical facility;
(viii) pharmaceutical administration facility; and
(ix) sterile product preparation facility.
(n) Class C pharmacy located in Utah engaged in:
(i) manufacturing;
(ii) producing;
(iii) wholesaling; and
(iv) distributing.

(o) Class D Out-of-state mail order pharmacies.
(p) Class E pharmacy including:
(i) medical gases providers; and
(ii) analytical laboratories.
(q) Utah Department of Corrections for the conduct of execution by the administration of lethal injection under its statutory authority and in accordance with its policies and procedures.
(2) A license may be restricted to the extent determined by the division, in collaboration with appropriate licensing boards, that a restriction is necessary to protect the public health, safety or welfare, or the welfare of the licensee. A person receiving a restricted license shall manufacture, produce, obtain, distribute, dispense, prescribe, administer, analyze, or conduct research with controlled substances only to the extent of the terms and conditions under which the restricted license is issued by the division.

R156-37-302. Qualifications for Licensure - Application Requirements.
(1) An applicant for a controlled substance license shall:
(a) submit an application in a form as prescribed by the division; and
(b) shall pay the required fee as established by the division under the provisions of Section 63-38-3.2.
(2) Any person seeking a controlled substance license shall:
(a) be currently licensed by the state in the appropriate professional license classification as listed in R156-37-301 and shall maintain that license classification as current at all times while holding a controlled substance license; or
(b) be engaged in the following activities which require the administration of a controlled substance but do not require licensure under Subsection (a):
(i) animal capture for transport or relocation as an employee or under contract with a state or federal government agency; or
(ii) other activity approved by the Division in collaboration with the appropriate board.
(3) The division and the reviewing board may request from the applicant information which is reasonable and necessary to permit an evaluation of the applicant's:
(a) qualifications to engage in practice with controlled substances; and
(b) the public interest in the issuance of a controlled substance license to the applicant.
(4) To determine if an applicant is qualified for licensure, the division may assign the application to a qualified and appropriate licensing board for review and recommendation to the division with respect to issuance of a license.

R156-37-303. Qualifications for Licensure - Site Inspections - Investigations.
The division shall have the right to conduct site inspections, review research protocol, conduct interviews with persons knowledgeable about the applicant, and conduct any other investigation which is reasonable and necessary to determine the applicant is of good moral character and qualified to receive a controlled substance license.

R156-37-304. Qualifications for Licensure - Examinations.
Each applicant for a controlled substance license shall be required to pass an examination administered at the direction of the division on the subject of controlled substance laws.

R156-37-305. Exemption from Licensure - Animal Euthanasia and Law Enforcement Personnel.
In accordance with Subsection 58-37-6(2)(d), the following persons are exempt from licensure under Title 58, Chapter 37:
(1) Individuals employed by an agency of the State or any of its political subdivisions, who are specifically authorized in writing by the state agency or the political subdivision to possess specified controlled substances in specified reasonable and necessary quantities for the purpose of euthanasia upon animals, shall be exempt from having a controlled substance license if the agency or jurisdiction employing that individual has obtained a controlled substance license, a DEA registration number, and

uses the controlled substances according to a written protocol in performing animal euthanasia.

(2) Law enforcement agencies and their sworn personnel are exempt from the licensing requirements of the Controlled Substance Act to the extent their official duties require them to possess controlled substances; they act within the scope of their enforcement responsibilities; they maintain accurate records of controlled substances which come into their possession; and they maintain an effective audit trail. Nothing herein shall authorize law enforcement personnel to purchase or possess controlled substances for administration to animals unless the purchase or possession is in accordance with a duly issued controlled substance license.

R156-37-401. Grounds for Denial of License - Disciplinary Proceedings.

Grounds for refusing to issue a license to an applicant, for refusing to renew the license of a licensee, for revoking, suspending, restricting, or placing on probation the license of a licensee, for issuing a public or private reprimand to a licensee, and for issuing a cease and desist order shall be in accordance with Section 58-1-401.

R156-37-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(1) a licensee with authority to prescribe or administer controlled substances:

(a) prescribing or administering to himself any Schedule II or III controlled substance which is not lawfully prescribed by another licensed practitioner having authority to prescribe the drug;

(b) prescribing or administering a controlled substance for a condition he is not licensed or competent to treat;

(2) violating any federal or state law relating to controlled substances;

(3) failing to deliver to the division all controlled substance license certificates issued by the division to the division upon an action which revokes, suspends or limits the license;

(4) failing to maintain controls over controlled substances which would be considered by a prudent practitioner to be effective against diversion, theft, or shortage of controlled substances;

(5) being unable to account for shortages of controlled substances any controlled substance inventory for which the licensee has responsibility;

(6) knowingly prescribing, selling, giving away, or administering, directly or indirectly, or offering to prescribe, sell, furnish, give away, or administer any controlled substance to a drug dependent person, as defined in Subsection 58-37-2(s), except for legitimate medical purposes as permitted by law;

(7) refusing to make available for inspection controlled substance stock, inventory, and records as required under these rules or other law regulating controlled substances and controlled substance records;

(8) failing to submit controlled substance prescription information to the database manager after being notified in writing to do so.

R156-37-601. Access to Records, Facilities and Inventory.

Applicants for licensure and all licensees shall make available for inspection to any person authorized to conduct an administrative inspection pursuant to Title 58, Chapter 37, these rules or federal law, to the extent they exist, during regular business hours and at other reasonable times in the event of an emergency, their controlled substance stock or inventory, records required under the Utah Controlled Substances Act and these rules or under the Federal controlled substance laws, and facilities related to activities involving controlled substances.

R156-37-602. Records.

(1) Records of purchase, distribution, dispensing, prescribing, and administration of controlled substances shall be kept according to state and federal law. Prescribing practitioners shall keep accurate records reflecting the examination, evaluation and treatment of all patients. Patient medical records shall accurately reflect the prescription or administration of controlled substances in the treatment of the patient, the purpose for which the controlled substance is utilized and information upon which the diagnosis is based. Practitioners shall keep records apart from patient records of each

controlled substance purchased, and with respect to each controlled substance, its disposition, whether by administration or any other means, date of disposition, to whom given and the quantity given.

(2) Any licensee who experiences any shortage or theft of controlled substances shall immediately file the appropriate forms with the Drug Enforcement Administration, with a copy to the division directed to the attention of the Investigation Bureau. He shall also report the incident to the local law enforcement agency.

(3) All records required by federal and state laws or rules must be maintained by the licensee for a period of five years. If a licensee should sell or transfer ownership of his files in anyway, those files shall be maintained separately from other records of the new owner.

(4) Prescription records may be maintained electronically so long as:

(a) the original of each prescription, including telephone prescriptions, is maintained in a physical file and contains all of the information required by federal and state law; and

(b) an automated data processing system is used for the storage and immediate retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, in accordance with federal guidelines.

(5) All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice.

(6) All records relating to Schedules III, IV and V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice.

R156-37-603. Restrictions Upon the Prescription, Dispensing and Administration of Controlled Substances.

(1) A practitioner may prescribe or administer the Schedule II controlled substance cocaine hydrochloride only as a topical anesthetic for mucous membranes in surgical situations in which it is properly indicated and as local anesthetic for the repair of facial and pediatric lacerations when the controlled substance is mixed and dispensed by a registered pharmacist in the proper formulation and dosage.

(2) A practitioner shall not prescribe or administer a controlled substance without taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug.

(3) When writing a prescription for a controlled substance, each prescription shall contain only one controlled substance per prescription form and no other legend drug or prescription item shall be included on that form.

(4) In accordance with Subsection 58-37-6(7)(f)(v)(D), unless the prescriber determines there is a valid medical reason to allow an earlier dispensing date, the dispensing date of a second or third prescription shall be no less than 30 days from the dispensing date of the previous prescription, to allow for receipt of the subsequent prescription before the previous prescription runs out.

(5) If a practitioner fails to document his intentions relative to refills of controlled substances in Schedules III through V on a prescription form, it shall mean no refills are authorized. No refill is permitted on a prescription for a Schedule II controlled substance.

(6) Refills of controlled substance prescriptions shall be permitted for the period from the original date of the prescription as follows:

(a) Schedules III and IV for six months from the original date of the prescription; and

(b) Schedule V for one year from the original date of the prescription.

(7) No refill may be dispensed until such time has passed since the date of the last dispensing that 80% of the medication in the previous dispensing should have been consumed if taken according to the prescriber's instruction.

(8) No prescription for a controlled substance shall be issued or dispensed without specific instructions from the prescriber on how and when the drug is to be used.

(9) Refills after expiration of the original prescription term requires the issuance of a new prescription by the prescribing practitioner.

(10) Each prescription for a controlled substance and the number of refills authorized shall be documented in the patient records by the prescribing practitioner.

(11) A practitioner shall not prescribe or administer a Schedule II controlled stimulant for any purpose except:

(a) the treatment of narcolepsy as confirmed by neurological evaluation;

(b) the treatment of abnormal behavioral syndrome, attention deficit disorder, hyperkinetic syndrome, or related disorders;

(c) the treatment of drug-induced brain dysfunction;

(d) the differential diagnostic psychiatric evaluation of depression;

(e) the treatment of depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as tricyclic antidepressants or MAO inhibitors;

(f) in the terminal stages of disease, as adjunctive therapy in the treatment of chronic severe pain or chronic severe pain accompanied by depression;

(g) the clinical investigation of the effects of the drugs, in which case the practitioner shall submit to the division a written investigative protocol for its review and approval before the investigation has begun. The investigation shall be conducted in strict compliance with the investigative protocol, and the practitioner shall, within 60 days following the conclusion of the investigation, submit to the division a written report detailing the findings and conclusions of the investigation; or

(h) in treatment of depression associated with medical illness after due consideration of other therapeutic modalities.

(12) A practitioner may prescribe, dispense or administer a Schedule II controlled stimulant when properly indicated for any purpose listed in Subsection (11), provided that all of the following conditions are met:

(a) before initiating treatment utilizing a Schedule II controlled stimulant, the practitioner obtains an appropriate history and physical examination, and rules out the existence of any recognized contraindications to the use of the controlled substance to be utilized;

(b) the practitioner shall not prescribe, dispense or administer any Schedule II controlled stimulant when he knows or has reason to believe that a recognized contraindication to its use exists;

(c) the practitioner shall not prescribe, dispense or administer any Schedule II controlled stimulant in the treatment of a patient who he knows or should know is pregnant; and

(d) the practitioner shall not initiate or shall discontinue prescribing, dispensing or administering all Schedule II controlled stimulants immediately upon ascertaining or having reason to believe that the patient has consumed or disposed of any controlled stimulant other than in compliance with the treating practitioner's directions.

R156-37-604. Prescribing of Controlled Substances for Weight Reduction or Control.

(1) A practitioner shall not prescribe, dispense or administer a Schedule II or Schedule III controlled substance for purposes of weight reduction or control.

(2) A prescribing practitioner may prescribe or administer a Schedule IV controlled substance in treating excessive weight leading to increased health risks only when all the following conditions are met:

(a) medication is used only as an adjunct to a comprehensive weight loss program based on supplemental weight loss activities including, but not limited to, changing lifestyle counseling, nutritional education, and a regular, individualized exercise regimen;

(b) prior to initiating treatment the prescribing practitioner shall:

(i) determine through thorough review of past medical records that the patient has made a substantial good-faith effort to lose weight in a comprehensive weight loss program without the use of controlled substances, and the previous regimen has not been effective;

(ii) obtain a complete history, perform a complete physical examination of the patient, and rule out the existence of any recognized contraindications to the use of the medication(s);

(iii) determine and document this assessment in the patient's medical record, that the health benefit to the patient greatly outweighs the possible risks of the medications prescribed; and

(iv) discuss with the patient the possible risks associated with the medication and have on record an informed consent which clearly documents that the long term effects of using controlled substances for weight loss or weight control are not known;

(c) throughout the prescribing period, the prescribing practitioner shall:

(i) supervise, oversee, and regularly monitor the patient, including his participation in supplemental weight loss activities, efficacy of the medication, and advisability of continuing to prescribe the weight loss or weight control medication; and

(ii) maintain a central medical record, containing at least, the goal of treatment or target weight, the ongoing progress toward that goal or maintenance of the weight loss, the patient's supplemental weight loss activities with documentation of compliance with the comprehensive weight loss program; and

(d) the prescribing practitioner shall immediately discontinue the weight loss medication in any of the following situations:

(i) the practitioner knows or should know that the patient is pregnant;

(ii) the patient has consumed or disposed of any controlled substance other than in compliance with the prescribing practitioner's directions;

(iii) the patient is abusing the controlled substance being prescribed for weight loss;

(iv) the patient develops a contraindication during the course of therapy; or

(v) the medication is not effective or that the patient is not abiding with and following through with the agreed upon comprehensive weight loss program.

R156-37-605. Emergency Verbal Prescription of Schedule II Controlled Substances.

(1) Prescribing practitioners may give a verbal prescription for a Schedule II controlled substance if:

(a) the quantity dispensed is only sufficient to cover the patient for the emergency period, not to exceed 72 hours;

(b) the prescribing practitioner has examined the patient within the past 30 days, the patient is under the continuing care of the prescribing practitioner for a chronic disease or ailment, or the prescribing practitioner is covering for another practitioner and has knowledge of the patient's condition; and

(c) a written prescription is delivered to the pharmacist within seven working days of the verbal order.

(2) A pharmacist may fill an emergency verbal or telephonic prescription from a prescribing practitioner for a Schedule II controlled substance if:

(a) the amount does not exceed a 72 hour supply; and

(b) the filling pharmacist reasonably believes that the prescribing practitioner is licensed to prescribe the controlled substances or makes a reasonable effort to determine that he is licensed.

R156-37-606. Disposal of Controlled Substances.

(1) Any disposal of controlled substances by licensees shall:

(a) be consistent with the provisions of 1307.21 of the Code of Federal Regulations; or

(b) require the authorization of the division after submission to the division to the attention of Chief Investigator of a detailed listing of the controlled substances and the quantity of each. Disposal shall be conducted in the presence of one of its investigators or a division authorized agent as is specifically instructed by the division in its written authorization.

(2) Records of disposal of controlled substances shall be maintained and made available on request to the division or its agents for inspection for a period of five years.

R156-37-607. Surrender of Suspended or Revoked License.

(1) Licenses which have been restricted, suspended or revoked shall be surrendered to the division within 30 days of the effective date of the order of restriction,

suspension or revocation. Compliance with this section will be a consideration in evaluating applications for relicensing.

R156-37-608. Herbal Products.

The division shall not apply the provisions of the Controlled Substance Act or these rules in restricting citizens or practitioners, regardless of their license status, from the sale or use of food or herbal products that are not scheduled as controlled substances by State or Federal law.

R156-37-609. Controlled Substance Database - Procedure and Format for Submission to the Database.

(1) In accordance with Subsections 58-37-7.5(6)(a), the format in which the information required under Section 58-37-7.5 shall be submitted to the administrator of the database is:

(a) electronic data via telephone modem;

(b) electronic data stored on floppy disk; or

(c) electronic data sent via electronic mail (e-mail) if encrypted and approved by the database manager.

(2) The required information may be submitted on paper, if the pharmacy or pharmacy group submits a written request to the division and receives prior approval.

(3) The division will consider the following in granting the request:

(a) the pharmacy or pharmacy group has no computerized record keeping system upon which the data can be electronically recorded; or

(b) the pharmacy or pharmacy group is unable to conform its submissions to the format required by the database administrator without incurring undue financial hardship.

(4) Each pharmacy or pharmacy group may submit the data either weekly, bi-weekly, or monthly. Any pharmacy which does not declare its intention for timely submission of data will be presumed to have chosen monthly submission.

(5) The format for submission to the database shall be in accordance with uniform formatting developed by the American Society for Automation in Pharmacy system (ASAP). The division may approve alternative formats or adjustments to be consistent with database collection instruments and contain all necessary data elements.

(6) The pharmacist-in-charge of each reporting pharmacy shall submit a report on a form approved by the division including:

(a) the pharmacy name;

(b) NABP number;

(c) the period of time covered by each submission of data;

(d) the number of prescriptions in the submission;

(e) the submitting pharmacist's signature attesting to the accuracy of the report; and

(f) the date the submission was prepared.

R156-37-610. Controlled Substance Database - Limitations on Access to Database Information - Standards and Procedures for Identifying Individuals Requesting Information.

(1) In accordance with Subsections 58-37-7.5(8)(a) and (b), the division director shall designate in writing those individuals within the division who shall have access to the information in the database.

(2) Personnel from federal, state or local law enforcement agencies may obtain information from the database if the information relates to a current investigation being conducted by such agency. The manager of the database may also provide information from the database to such agencies on his own volition when the information may reasonably constitute a basis for investigation relative to violation of state or federal law.

(3) In accordance with Subsections 58-37-7.5(5)(c), (6)(b), (7)(b), and (8)(d) and (e), the database manager may provide information from the database to licensed practitioners having authority to prescribe controlled substances and to licensed pharmacists having authority to dispense controlled substances. The database manager may provide the information on his own volition to accomplish the stated purposes set forth in Subsection 58-37-7.5(5).

(4) Any individual may request information in the database relating to that individual's receipt of controlled substances. Upon request for database information on an individual who is the recipient of a controlled substance prescription entered in the database, the manager of the database shall make available database information exclusively relating to that particular individual under the following limitations and conditions:

(a) The requestor seeking database information personally appears before the manager of the database, or a designee, with picture identification confirming his identity as the same person on whom database information is sought.

(b) The requestor seeking database information submits a signed and notarized request executed under the penalty of perjury verifying his identity as the same person on whom database information is sought, and providing their full name, home and business address, date of birth, and social security number.

(c) The requestor seeking database information presents a power of attorney over the person on whom database information is sought and further complies with the following:

(i) submits a signed and notarized request executed by the requestor under the penalty of perjury verifying that the grantor of the power of attorney is the same person on whom database information is sought, including the grantor's full name, address, date of birth, and social security number; and

(ii) personally appears before the manager of the database with picture identification to verify personal identity, or otherwise submits a signed and notarized statement executed by the requestor under the penalty of perjury verifying his identity as that of the person holding the power of attorney.

(d) The requestor seeking database information presents verification that he is the legal guardian of an incapacitated person on whom database information is sought and further complies with the following:

(i) submits a signed and notarized request executed by the requestor under the penalty of perjury verifying that the incapacitated ward of the guardian is the same person on whom database information is sought, including the ward's full name, address, date of birth, and social security number; and

(ii) personally appears before the manager of the database with picture identification to verify personal identity, or otherwise submits a signed and notarized statement executed by the requestor under the penalty of perjury verifying his identity as that of the legal guardian of the incapacitated person.

(e) The requestor seeking database information shall present a release-of-records statement from the person on whom database information is sought and further complies with the following:

(i) submits a verification from the person on whom database information is sought consistent with the requirements set forth in paragraph (4)(b);

(ii) submits a signed and notarized release of records statement executed by the person on whom database information is sought authorizing the manager of the database to release the relevant database information to the requestor; and

(iii) personally appears before the manager of the database with picture identification to verify personal identity, or otherwise submits a signed and notarized statement executed by the requestor under the penalty of perjury verifying his identity as that of the requestor identified in the release of records;

(5) Before data is released upon oral request, a written request may be required and received.

(6) Database information may be disseminated either orally, by facsimile or by U.S. mail.

(7) The Utah Department of Health may access Database information for purposes of scientific study regarding public health. To access information, the scientific investigator must:

(a) show the research is an approved project of the Utah Department of Health;

(b) provide a description of the research to be conducted, protocols for the project and a description of the data needs from the Database;

(c) provide assurances and a plan that demonstrates all Database information will be maintained securely, with access only permitted by the scientific investigator;

(d) provide for electronic data to be stored on a stand alone database computer system with access only allowed by the scientific investigator; and
(e) pay all relevant expenses for data transfer and manipulation.

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